K132599

510(k) Summary

FEB 2 5 2014

[as required by section 807.92(c)]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

General Information

Submitted by:	Millennium Company LLC 2524 Lake Lansing Road Lansing, MI 48912 Phone: +1 (517) 282-3811 Fax: +1 (517) 485-3763 Email: drbillv@smilebond.com
Contact Person:	Stephen J. Goldner, JD, RAC Regulatory Affairs Associates, Inc. 40701 Woodward Avenue, Suite 102 Bloomfield Hills, MI 48304 Phone: +1 (248) 712-0356 Fax: +1 (203) 413-4320 Email: sgoldner@regaffairs.net
Date Prepared:	February 6, 2014

Device Name

Trade Name:	Fast-Set Bite Registration Material; SmileBond System
Common Name(s):	Impression Material

Classification

Regulation:	21 CFR §872.3660
Class:	II
Product Code:	ELW
Classification Name:	Impression material
Regulation Name:	Iimpression material

Predicate Devices

Silicone Impression Material	K801830	Crown Delta
TempSpan Clear Matrix Material	K120013	Pentron Clinical

Device Description

SmileBond System is a patented process for the delivery of dental bonding composites. The SmileBond process is indicated for both cosmetic enhancement of the smile, and functional improvement of the bite (or chewing system).

Indication for Use

SmileBond Systems Fast Bite Registration Material impression material is indicated for making impressions of the teeth and gums of patients requiring enhancement of the smile and for bite alignment.

Intended Use

Fast-Set Bite Registration Material is intended for the enhancement of the smile and bite alignment. SmileBond System is intended for

- cosmetic correction;
- malpositioned teeth;
- tooth discoloration, incorrect shading;
- anatomical malformation;
- attrition, abrasion, erosion; and
- decay repair.

Comparison to Predicate Devices

TempSpan Clear Matrix Material is a clear, medium viscosity vinyl polysiloxane material that reproduces fine detail for the fabrication of extremely accurate provisional restorations

Crown Delta's silicone impression material will be used for making impressions of the teeth and gums of patients requiring models for study and/or for production of restorative prosthetic devices. The impression material is intended to be applied via a dual barrel cartridge system either into an impression tray or directly onto the patient's teeth.

Fast-Set Bite Registration is a silicone impression material intended to be placed on an impression tray to reproduce the structures of the teeth and gums of patients requiring the enhancement of the smile and for bite alignment. The impression material is intended to be applied via a dual barrel cartridge system into an impression tray. The clear impression material is used in the lab to make an accurate impression of the final wax up. Once the impression material is set and slightly modified it is taken to the

mouth for use in the transfer bonding process.

The Fast Bite Registration Material is manufactured by Crown Delta under its 510(k) K801380 for Millennium Company. The product is labeled with the Own Brand Label (OBL) for SmileBond System.

Conclusion

The SmileBond System kit is comprised of legally marketed devices. The SmileBond process does not affect the substantial equivalence of the Fast-Set Bite Registration Material to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Millennium Company LLC
C/O Mr. Stephen J. Goldner, JD, RAC
Regulatory Affairs Associates, Inc.
40701 Woodward Avenue, Suite 102
Bloomfield Hills, MI 48304

Re: K132599
Trade/Device Name: SmileBond System: Fast-Set Bite Registration Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW, OFW
Dated: November 27, 2013
Received: December 6, 2013

Dear Mr. Goldner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Fonn Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See *PRA Statement on last page.*

510(k) Number *(if known)*
K132599

Device Name
SmileBond System Fast Bite Registration Material

Indications for Use *(Describe)*

SmileBond Systems Fast Bite Registration Material impression material is used for making impressions of the teeth and gums of patients requiring enhancement of the smile and for bite alignment.

Type of Use *(Select one or both, as applicable)*

Prescription Use (Part 21 CFR 801 Subpart D) D Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Mary S. Runner -S
2014.02.27
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